

REMARKS

The Office Action mailed March 12, 2002, has been received and its contents carefully noted. In order to advance prosecution, proposed claim changes were prepared and were discussed with the Examiner, Dr. Liliana Di Nola-Baron, and her supervisor, Mr. Speer, during the personal interview of August 28, 2002, for which Applicants express thanks. In this Amendment, claims 15-39 have been cancelled without prejudice or disclaimer, new claims 40-58 have been added to the Application, and the title and abstract have been replaced in order to reflect the subject matter of the new claims.

Support for the new claims is found in the Application as follows:

Claim 40: claims 2 and 39; page 10, lines 4 and 5; Examples 4, 5, and 7; Figure 6; page 23, lines 8-20, especially lines 18-20.

Claims 41, 47, and 54: page 11, lines 4-11, especially line 8.

Claims 42, 48, and 55: claims 3 and 8.

Claims 43, 49, and 56: claim 5.

Claims 44, 50, and 57: claim 6.

Claims 45 and 52: claims 4 and 7.

Claims 46 and 53: page 1, lines 4-9, and page 4, line 20.

Claims 51 and 58: claims 4 and 7.

Claims 40-58 are now pending in the Application and are submitted to be in allowable condition for the reasons given in the following.

Applicants thank the Examiner and her supervisor for the courtesy extended to Applicants' Patent Counsel during the personal interview of August 28, 2002. The claims and arguments presented a Proposed Amendment were discussed in detail during the interview. No agreement was reached that the proposed new claims distinguish over the combination of Provonchee et al. and Jamas et al.

The Examiners commented that the coating agent claims were viewed as simple composition claims so that the use as a "coating agent" was given no patentable weight and that there are many prior art references available which teach cell residues of enzyme treated (or enzyme and acid treated) yeast comprised of glucan, mannan, and chitin. Counsel responded that there are no such references of record at this time and pointed out that Applicants are responding to the applied prior art as stated in the rejection of record. The Examiners stated that they intend to conduct a further search of the art and do not expect to have any trouble finding numerous prior art references on point because the Examiners considered that the claims are too broad. The Examiners' handwritten comments in the Interview Summary state:

"The amendment proposed by Applicant has been discussed. It is the view of the examiners that the newly proposed claims are too broad and some additional limitations such as the ratio of the components and the time at which dissolution starts, should be included."

Counsel argued that Provonchee et al. and Jamas et al. employ only compositions containing glucan, but not glucan, mannin, and chitin. The Examiners took the position that, if recitation of these three constituents was included to distinguish over the combination of Provonchee et al. and Jamas et al., the ratio of the components, namely, glucan, mannan, and

chitin, was considered important to dissolution properties and should be recited in the claims. Counsel disagreed because the specification describes various yeast types which would inherently have certain ratios of these constituents (see the last two lines of page 8) so that Applicants should not be limited to any particular yeast or any particular ratio.

The Examiners took the additional position that the time at which dissolution starts should be recited in the claims. Counsel disagreed because Figures 1-8 show widely varying start times depending on various factors described in the working examples.

The Examiners took the position that they considered the expression "having a reduced amount of internal soluble cell constituents" to be indefinite because no amount is stated and because what is meant by "reduced" has not been defined. Counsel pointed out that no such objection/rejection is presently of record.

The rejection of claims 15-39 under 35 U.S.C. §112, second paragraph, is moot in view of cancellation of these claims.

While Applicants consider that "**plastic fluid**" is a term of art which would be known by an artisan, the phrase "plastic fluid" has been deleted from the claims, in view of the Examiner's objection, without prejudice on the grounds that this recitation is not needed to distinguish over the prior art presently applied against the claims.

The rejection of claims 15-39 under 35 U.S.C. §103 as being unpatentably obvious over Provonchee et al. in view of Jamas et al. (US 6,020,324) is moot in view of cancellation of claims 15-28 and is respectfully traversed for new claims 40-58. The Examiner relies on

Provonchee et al. as providing controlled release pharmaceuticals by coating pharmaceuticals with acid-treated yeast cell wall components. The Examiner acknowledges that Provonchee et al. do not disclose a plasticizer for which reason the Examiner relies on Jamas et al.

Applicants do not agree that the combined disclosures of Provonchee et al. and Jamas et al. set out a *prima facie* case of obviousness against new claims 40-58 because the combined disclosures do not meet Applicants' claims. Neither reference taken alone or in combination is submitted to teach or suggest Applicants' novel use of the concentration of the acidic solution used to treat the cell residue of yeast to control the time at which the coated material begins to dissolve in a solvent , process for producing a coated material, and coated material by the process.

The present invention employs yeast cell wall fractions for coating a solid material to obtain a coated material having desirable properties. Applicants consider that Applicants' use of yeast cell wall fractions as a coating agent to obtain the advantages described in the present Application is neither taught nor suggested by the prior art (see claims 40-44).

Applicants have cancelled the coating agent claims in view of the Examiner's position that Applicants' coating agent is a known material even though it is Applicants' position that the glucan materials of the applied references, Provonchee et al. and Jamas et al. are distinguishable.

Applicants consider, however, that Applicants' use of compositions comprising yeast cell wall fractions as a coating agent to obtain the advantages described in the present Application is new and unobvious. It is well settled that a new use for even a known composition is patentable (see 35 U.S.C. §101).

Applicants found that cell residue of yeast which has been treated with enzymes and water to remove internal soluble cell constituents can be used as a coating agent which has good physical properties of non-stickness, extremely low oxygen or other gas permeability and moisture permeability.

Applicants additionally found that the time at which dissolution of a coating on a solid material begins may be controlled by changing the concentration of an acidic solution during acid-treatment of cell residue of yeast. This was considered surprising and is discussed in the Application on page 11, line 16, through page 12, line 17, in the Examples, and in the Figures (see, for example, Figures 4, 5, and 7).

Provonchee et al. disclose a beta-1,3-glucan polysaccharide gel composition prepared by dissolving the beta-1,3-glucan polysaccharide in an aqueous alkaline medium. The gels may be used as coatings for biological materials (see the abstract).

Provonchee et al. do not teach or suggest Applicants' use of a coating agent comprised of yeast cell wall fractions to coat a solid material so that the time at which dissolution of the coating on a solid material begins may be controlled by changing the concentration of an acidic solution during acid-treatment of the enzyme-treated cell residue of yeast .

Moreover, the substance used as a coating agent in Provonchee et al. is **not** a yeast cell wall residue. It is an isolated polysaccharide compound consisting of beta-1,3-glucan.

Jamas et al. relates to a composition and method utilizing **yeast glucan as a dietary additive**. Jamas et al. relates to compositions useful for treatment of dietary disorders. Though Jamas et al. refer to coating material and plasticizer, these are mentioned only in the context of making tablets out of glucan compositions for oral administration.

While the Examiner maintains that Jamas et al. teach use of yeast β -glucan as a coating material Applicants respectfully traverse this position and respectfully direct the Examiner's attention to column 7, lines 13-19, which state:

"For example, a composition to be administered orally in tablet or powder form can include, in addition to whole β -glucan, a filler ..., a binder ..., an adjuvant ..., a flavoring agent, a coloring agent, and/or a coating material (e.g., wax or plasticizer) and/or other nutritional supplements."

The plain meaning of the foregoing sentence is that a coating material may be included in a composition in addition to β -glucan, not that β -glucan is a coating material. Moreover, Jamas et al. read as a whole teaches β -glucan used as a nutritional supplement (see, for example, the title and abstract), hence, the last phrase in the sentence quoted above, *"and/or other nutritional supplements."* Thus, it is Applicants' position that Jamas et al. do not teach or suggest Applicants' novel use as claimed in claims 40-44.

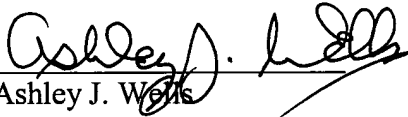
Further, Applicants consider that the process for producing a coated material claims (claims 45-50 and 52-57) and the coated material claims (claims 51 and 58) are novel and unobvious for the same reasons as for the use claims. None of the prior art of record teach or suggest Applicants' use, process for producing a coated material, and coated material by the process.

Applicants respectfully submit that the disclosure of Jamas et al. does not supply the disclosure missing in Provonchee et al. so that the combination of Provonchee et al. and Jamas et al. may not be said to render the present invention claimed in claims 40-58 obvious.

In view of the foregoing amendments and remarks, it is requested that the rejections of record be reconsidered and withdrawn, that new claims 40-58 be allowed, and that the Application be found to be in allowable condition.

Should the Examiner not find the Application to be in allowable condition or believe that a further conference would be of value in expediting the prosecution of the Application, Applicants request that the Examiner telephone undersigned Counsel to discuss the case and afford Applicants an opportunity to submit any Supplemental Amendment that might advance prosecution and place the Application in allowable condition.

Respectfully submitted,


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